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**Test and Evaluation Report
of the IVAC[®] Volumetric Infusion
Pump Model 580+EE**

By

**James E. Bruckart (Project Officer)
and
Joseph R. Licina (Project Officer)**

Biodynamics Research Division

Bill Olding (UES)

Martin Quattlebaum (UES)

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Reviewed:



ROBERT W. WEIEN
MAJ, MC, SFS
Director, Biodynamics
Research Division

Released for publication:



ROGER W. WLEEY, O.D., Ph.D.
Chairman, Scientific
Review Committee



DAVID H. KARNEY
Colonel, MC, SFS
Commanding

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19. ABSTRACT (Continue on reverse if necessary and identify by block number) The IVAC® Volumetric Infusion Pump, Model 580+EE, was tested for electromagnetic interference/compatibility in the UH-60A helicopter under the U.S. Army Program for Testing and Evaluation of Equipment for Aeromedical Operations. The tests were conducted using current military and industrial standards and procedures for electromagnetic interference/compatibility and human factors. The IVAC® Model 580+EE did not perform properly in the altitude chamber, vibration test, and excess electromagnetic emissions make it ineligible for an airworthiness release. Therefore, the unit is not considered compatible with U.S. Army aeromedical aircraft.					
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Section 1. Executive digest

The Army program for Test and Evaluation of Aeromedical Equipment uses existing military standards (MIL-STD) and collective professional expertise to test and evaluate selected medical equipment proposed for use aboard Army aircraft. Equipment meeting these standards ensures the safety of the crew, patients, and aircraft by eliminating risks due to: (1) Interference by the medical equipment with aircraft systems/subsystems operation, (2) the aircraft system's interference with the operation of the medical equipment, (3) the medical equipment's susceptibility to environmental exposure, or (4) physical and/or functional incompatibility while in use on board selected rotary-wing aircraft. This program tests both developmental and nondevelopmental (off the shelf) medical equipment destined for use aboard Army medical evacuation aircraft.

1.1 TEST OBJECTIVES

1.1.1 To determine if the medical equipment is complete and operational per the manufacturer's operating instructions.

1.1.2 To ensure the electrical safety of the medical equipment.

1.1.3 To ensure the equipment will function as designed throughout the rated battery operation time.

1.1.4 To ensure the safety of the operator, the patient, and the aircrew.

1.1.5 To assess design considerations which potentially could contribute to an operator error.

1.1.6 To determine if the medical equipment can function as designed in a low pressure environment.

1.1.7 To determine the ability of the medical equipment to withstand the vibrational stresses expected in a rotary-wing flight environment without degradation or malfunction.

1.1.8 To determine the ability of the medical equipment to be stored and operated in a high-temperature environment.

1.1.9 To determine the ability of the medical equipment to be stored and operated in a low-temperature environment.

1.1.10 To determine the ability of the medical equipment to operate satisfactorily for short periods during exposure to high humidity conditions.

1.1.11 To assess the levels of electromagnetic emissions produced by the medical equipment within selected frequency ranges.

1.1.12 To assess the minimum electromagnetic susceptibility levels of the medical equipment within selected frequency ranges.

1.1.13 To assess the physical and/or functional compatibility of the medical equipment while in use on board the aircraft.

1.1.14 To assess the electromagnetic interference (EMI) and electromagnetic compatibility (EMC) characteristics of the medical equipment with the host aircraft and its installed systems.

1.2 TESTING AUTHORITY

Research and Technology Work Unit Summary, dated 5 October 1989. Project number 3M463807D836, titled, Army Program for Testing and Evaluation of Equipment for Aeromedical Operations.

1.3 SCOPE

1.3.1 This test was conducted at the United States Army Aeromedical Research Laboratory (USAARL) at Fort Rucker, Alabama.

1.3.2 The USAARL UH-60A aircraft, serial number 88-26069, with subsystems delineated in paragraph 3.2.2, was available for flight test of the IVAC® Volumetric infusion pump*, model 580+EE. The unit was not approved for flight testing.

1.3.3 Laboratory testing was accomplished at USAARL using government furnished equipment (GFE) by Universal Energy Systems, Inc. (UES), under contract No. DAMD 17-86-C-6215.

1.3.4 The following tests were accomplished: Acceptance inspection, equipment training, electromagnetic compatibility, human factors and safety, and environmental compatibility.

1.4 MATERIAL DESCRIPTION

The IVAC® Model 580+EE Volumetric infusion pump is electrically driven and designed to regulate IV fluids on a semiautomatic basis. Membrane switches on the front of the infusion pump allow the user to set the primary and secondary rate and volume of fluid to be administered. The rate adjustment range is from 1 to 500 ml/hr. The primary volume to be infused may be adjusted from 1 to 9999 milliliters and the secondary volume may be adjusted from 1 to 999 milliliters. When the selected volume

* See list of manufacturers

has been delivered, an audio alarm is activated and the IVAC® 580+EE reverts to a "keep vein open" delivery rate of 5 ml/hr. A locking clear blue plastic door protects the administration set and the control mechanism. The infusion pump is automatically shut off if the door is opened during the infusion. A pole clamp, ac power receptacle, flow sensor storage bracket, flow sensor receptacle, and an ac line circuit breaker are located on the back panel. The only administration set that will function properly with the IVAC® 580+EE is the IVAC® "Type S" administration set.

1.5 SUMMARY

1.5.1 Laboratory testing

1.5.1.1 Battery life evaluation: The IVAC® Model 580+EE was operated on a fully-charged battery at 125 ml/hr at room temperature (75 degrees F and 51% RH). The fully-charged IVAC® Model 580+EE averaged 7 hours and 8 minutes of operation. The battery is rated for 6 hours of operation. This exceeds the manufacturer's specification.

1.5.1.2 Electrical safety evaluation: All measurements were within acceptable limits. No unsafe qualities were found in the IVAC® Model 580+EE. The limits for currents and resistances were in accordance with (IAW) the limits specified in TB-38-750-2, April 1987.

1.5.1.3 Human factors evaluation: The IVAC® Model 580+EE was found to be satisfactory in all major categories of the evaluation criteria with one exception. The red light emitting diode displays do not have an intensity control.

1.5.1.4 Environmental tests: The IVAC® Model 580+EE can be expected to perform in a variety of environmental conditions. Its performance was found to be satisfactory in all stages of the environmental testing except the altitude, vibration tests, high temperature (operating), and humidity tests. The IVAC® 580+EE Infusion Pump's performance was found to be unsatisfactory during the altitude test. When chamber pressure was reduced, the soft plastic vented "Type S" administration set started to expand in the low pressure environment. At altitude, a large number of air bubbles were present in the administration set and were not detected by the unit. During vibrations on the Y and Z axis, high temperature operation, and high humidity operation, the infusion pump flashed error alarms which indicate an internal malfunction as described in the operator's manual. The requirements for environmental tests are established in MIL-STD-810D, methods 500.2 (altitude), 514.3 (vibration), 501.2 (high temperature), 502.2 (low temperature), and 507.2 (humidity).

1.5.1.5 Radiated emissions tests (RE02): The IVAC® Model 580+EE may be unsatisfactory for use in certain EMI sensitive environments. Narrowband (NB) and broadband (BB) radiated emissions were detected in the test frequency ranges. Some narrowband and broadband emissions exceeded the test limits. Emission limits are set forth in MIL-STD-461A, Notice 4.

1.5.1.6 Radiated susceptibility test (RS03): The IVAC® Model 580+EE was found to be susceptible to radio frequency interference in the testing range and magnitude.

1.5.1.7 Conducted emissions test (CE01, CE02, and CE04): Narrowband and broadband emissions exceeding specification limits were detected.

1.5.1.8 Conducted susceptibility test (CS02 and CS06): The IVAC Model 580+EE Infusion Pump was not tested for susceptibility to conducted radio frequency interference. The test signals could not be detected on the infusion pump power line due to conducted emissions from the infusion pump.

1.5.2 In-flight testing

In-flight testing of the IVAC® Model 580+EE Volumetric Infusion Pump could not be accomplished. Request for Airworthiness Release was denied by the U.S. Army Aviation Systems Command due to excess electromagnetic emissions discovered during laboratory testing.

1.6 CONCLUSIONS

Since the IVAC® Model 580+EE did not perform properly in the altitude chamber, vibration test, and excess electromagnetic emissions make it ineligible for an airworthiness release, the unit is not considered compatible with the U.S. Army medical evacuation UH-60A Black Hawk with the subsystems listed in paragraph 3.2.2.

Section 2. Subtests

2.1 INITIAL INSPECTION

2.1.1 Objective

To determine if the IVAC® Model 580+EE is complete and operational for testing per the manufacturer's operating instructions.

2.1.2 Criteria

2.1.2.1 The physical inventory is conducted solely for investigation and documentation.

2.1.2.2 The IVAC® Model 580+EE will display consistent and accurate measurements as an acceptable performance test.

2.1.3 Test procedure

2.1.3.1 A complete physical inventory of the IVAC® Model 580+EE was completed per the manufacturer's equipment list.

2.1.3.2 An operational validation test of the IVAC® Model 580+EE was conducted per the manufacturer's operating instructions by USAARL's medical maintenance personnel.

2.1.4 Test findings

2.1.4.1 The IVAC® Model 580+EE was inventoried and found to be complete.

2.1.4.2 The IVAC® Model 580+EE operated as prescribed in the manufacturer's operating manual. Criteria met.

2.2 BATTERY LIFE EVALUATION (Laboratory)

2.2.1 Objective

To ensure the equipment will function as designed throughout the rated battery operation time.

2.2.2 Criterion

Verify manufacturer's specified full power internal battery life expectancy of 6 hours operation at 125 ml/hr infusion rate.

2.2.3 Test procequire

2.2.3.1 Charging and operation cycles were conducted in ambient room conditions.

2.2.3.2 The IVAC® Model 580+EE was operated continuously using its fully-charged internal battery at 125 ml/hr infusion rate until a low battery indication occurred. The depletion time was noted and the battery was recharged. This procedure was repeated three times.

2.2.4 Test findings

The test was conducted using the fully-charged internal battery. The average operating time in testing was 7 hours and 6 minutes at room temperature. This exceeds manufacturer's specification of 6 hours. Criterion met.

2.3 ELECTRICAL SAFETY EVALUATION

2.3.1 Objective

To ensure the electrical safety of the IVAC® Model 580+EE by evaluation of case-to-ground resistance and case-to-ground current leakage.

2.3.2 Criterion

The IVAC® Model 580+EE shall meet the standards established in Technical Bulletin Number 38-750-2, April 1987 for electrical safety of medical equipment.

2.3.3 Test procedure

Measurements in the electrical safety evaluation were made with a Neurodyne-Dempsey model 431F electrical safety analyzer*, IAW the procedures described in Technical Bulletin (TB) Number 38-750-2. Case-to-ground resistance and various case-to-ground leakage currents were measured. Leakage currents were measured using a 10 by 20 centimeter aluminum foil sheet taped flush to the equipment case. Checks were made for safety concerns such as case integrity, breaks in power cord insulation, and connectors.

2.3.4 Test findings

Grounding conductor resistance was 70.5 milliohms and maximum case leakage current was 0.3 microamperes. These measurements are below the limits specified in TB 38-750-2 and NAFP 99. Criterion met.

2.4 HUMAN FACTORS EVALUATION (Laboratory)

2.4.1 Objectives

2.4.1.1 To assure the safety of the operator, the potential patient, and the aircrew.

2.4.1.2 To assess the design considerations which could potentially contribute to an operator error.

2.4.2 Criterion

The IVAC® Model 580+EE must be rated satisfactory in all major categories of the evaluation. These include visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.4.3 Test procedure

2.4.3.1 The evaluation was conducted in a laboratory under fluorescent lighting and ambient room conditions.

2.4.3.2 The IVAC® Model 580+EE was operated according to prescribed instructions through its full range of functions.

2.4.4 Test finding

The IVAC® Model 580+EE was found to be satisfactory in all of the evaluation criteria with one exception. The red LED displays do not have an intensity control. Criterion partially met.

2.5 ALTITUDE (LOW PRESSURE) TEST [IAW MIL-STD-810D, METHOD 500.2]

2.5.1 Objective

To determine if the IVAC® Model 580+EE can function as designed in a low-pressure environment.

2.5.2 Criterion

The IVAC® Model 280E will display consistent and accurate performance while exposed to an altitude equivalency of 15,000 feet above sea level.

2.5.3 Test procedure

2.5.3.1 A pretest performance check was conducted to ensure proper operation of the IVAC® Model 580+EE.

2.5.3.2 The altitude test was performed in a Tenney Engineering model 64S altitude chamber*. This test is based on MIL-STD-810D, Method 500.2. The IVAC® Model 580+EE was operated at 70 ml/hr and placed on the floor of the chamber. Chamber pressure was decreased to 420 mmHg (15,000 ft equivalent altitude) over a 15-minute period, held constant for 60 minutes, then raised, at 1500 fpm, to ambient conditions (760 mmHg) over a 10-minute period. There were no provisions for the control of temperature or humidity inside this chamber.

2.5.3.3 A posttest performance check was conducted to ensure proper operation of the IVAC® Model 580+EE after the exposure to low pressure.

2.5.4 Test findings

2.5.4.1 The pretest performance check met criterion 2.1.2.2.

2.5.4.2 Variation in pressure caused the drip chamber of the "S" administration set to become filled with bubbles, but no error condition was detected by the unit. When the unit was returned to ambient conditions the drip chamber continued to be filled with bubbles, but no error condition was detected by the unit. Criterion not met.

2.5.4.3 The posttest performance check met criterion 2.1.2.2.

2.6 VIBRATION TEST [IAW MIL-STD-810D, METHOD 514.3]

2.6.1 Objective

To determine the ability of the IVAC® Model 580+EE to withstand the vibrational stresses expected in a rotary-wing environment without degradation or malfunction.

2.6.2 Criterion

The IVAC® Model 580+EE will remain operational and be able to display consistent and accurate measurements while exposed to vibrational stresses.

2.6.3 Test procedure

2.6.3.1 A pretest performance check was conducted to ensure proper operation of the IVAC® Model 580+EE.

2.6.3.2 The vibration test was performed using an Unholtz-Dickey model TA115-40/CSTA vibration test system*. It is a single-axis system with an electromagnetic driver unit. The test consisted of sinusoidal vibrations superimposed on random vibrations over a frequency range of 500 Hz, as shown below. These vibrations are

derived from measurements taken on the floor under the copilot's seat in a UH-1 helicopter traveling at 120 knots. The reference spectrum breakpoints are from MIL-STD-810D, Method 514.3; reference spectrum levels are based on field measurements with a conservatism factor of 1.5. Independent tests were conducted in the X, Y, and Z axes.

Z-axis

duration: 60 minutes
broadband intensity: 0.4506 G_{rms}
random vibration: initial slope : 99.00 dB/oct
5 Hz level: 0.00006210 $G_{sqr/Hz}$
100 Hz level: 0.0006210 $G_{sqr/Hz}$
300 Hz level: 0.0006210 $G_{sqr/Hz}$
500 Hz level: 0.00006210 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .5450 G_{pk} at 11.25 Hz
.1690 G_{pk} at 22.50 Hz
.1200 G_{pk} at 33.75 Hz
.0310 G_{pk} at 45.00 Hz
.0530 G_{pk} at 56.25 Hz

X and Y axes

duration: 60 minutes each
broadband intensity: 0.3099 G_{rms}
random vibration: initial slope: 99.00 dB/oct
5 Hz level: 0.00002920 $G_{sqr/Hz}$
100 Hz level: 0.0002920 $G_{sqr/Hz}$
300 Hz level: 0.0002920 $G_{sqr/Hz}$
500 Hz level: 0.00002920 $G_{sqr/Hz}$
final slope: -99.00 dB/oct
sinusoidal vibration: .3200 G_{pk} at 11.25 Hz
.0670 G_{pk} at 22.50 Hz
.0950 G_{pk} at 33.75 Hz
.0350 G_{pk} at 45.00 Hz
.0770 G_{pk} at 56.25 Hz

The IVAC® Model 580+EE was strapped to the vibration table fixture, and its performance was evaluated before, during, and after exposure to vibration.

2.6.3.3 A posttest performance check was conducted to ensure proper operation of the IVAC® Model 580+EE.

2.6.4 Test findings

2.6.4.1 The pretest performance check met criterion 2.1.2.2.

2.6.4.2 No failures in the performance of the IVAC® Model 580+EE occurred before or after exposure to vibration. During vibrations on the Y and Z axis tests, the infusion pump flashed

error alarms which indicate an internal malfunction as described in the operator's manual. Criterion not met.

2.6.4.3 The posttest performance check met criterion 2.1.2.2.

2.7 HIGH TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 501.2]

2.7.1 Objective

To determine the ability of the IVAC® Model 580+EE to be stored and operated in a high-temperature environment.

2.7.2 Criteria

2.7.2.1 The IVAC® Model 580+EE will display consistent and accurate measurements during the high-temperature operation check.

2.7.2.2 The IVAC® Model 580+EE will display consistent and accurate measurements after the high-temperature storage cycle.

2.7.3 Test procedure

2.7.3.1 A pretest performance check was conducted to ensure proper operation of the IVAC® Model 580+EE.

2.7.3.2 The high-temperature test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 501.2. For the high-temperature operation test, the IVAC® Model 580+EE was turned on at 70 ml/hr, with the drip chamber 36 inches above the venipuncture site, and placed on the floor of the environmental chamber. The chamber temperature was raised to 49°C and the humidity was stabilized at a maximum of 20 percent RH within 15 minutes. The environmental control system is capable of regulating temperature within $\pm 2^\circ\text{C}$ and humidity within ± 5 percent RH. Temperature and humidity were held constant for 2 hours. At 30-minute intervals, the chamber door was opened briefly to minimize the change in chamber conditions during performance checks. After the operational test, the IVAC® Model 580+EE was allowed to return to ambient conditions over a 30-minute period.

2.7.3.3 A posttest performance check was conducted to ensure proper operation of the IVAC® Model 580+EE.

2.7.3.4 The IVAC® Model 580+EE was stored (not operated) at temperatures of 63°C for 1 hour, 71°C for 4 hours, then again at 63°C for 1 hour. The chamber and IVAC® Model 580+EE then were returned to ambient conditions over a 30-minute period.

2.7.3.5 A poststorage performance check was conducted to ensure proper performance of the IVAC® Model 580+EE.

2.7.4 Test findings

2.7.4.1 The pretest performance check met criterion 2.1.2.2.

2.7.4.2 The infusion pump flashed error alarms which indicate and internal malfunction during the high temperature operating test. Criterion not met.

2.7.4.3 The posttest performance check met criterion 2.1.2.2.

2.7.4.4 The IVAC® Model 580+EE functioned properly after the high-temperature storage test. Criterion met.

2.8 LOW TEMPERATURE TEST [IAW MIL-STD-810D, METHOD 502.2]

2.8.1 Objective

To determine the ability of the IVAC® Model 580+EE to be stored and operated in a low-temperature environment.

2.8.2 Criteria

2.8.2.1 The IVAC® Model 580+EE will display consistent and accurate performance during the low-temperature operation check.

2.8.2.2 The IVAC® Model 580+EE will display consistent and accurate performance after the low-temperature storage cycle.

2.8.3 Test procedure

2.8.3.1 A pretest performance check was conducted to ensure proper operation of the IVAC® Model 580+EE.

2.8.3.2 The IVAC® Model 580+EE was placed on the floor of the environmental chamber and the temperature was lowered to 0°C within 25 minutes. The environmental control system is capable of regulating temperature within 2°C. Humidity cannot be controlled in the chamber at freezing temperatures. The temperature was held constant for 2 hours. Every 30 minutes, the chamber door was opened briefly to minimize the change in chamber conditions and a performance check was conducted. The chamber temperature then was raised to ambient temperature within a 30-minute period.

2.8.3.3 A posttest performance check was conducted to ensure proper operation of the IVAC® Model 580+EE.

2.8.3.4 The IVAC® Model 580+EE was "stored" in a nonoperational mode. The IVAC® Model 580+EE was placed on the floor of the environmental test chamber and the temperature was lowered to -46°C for 6 hours. The chamber then was raised to ambient temperature over a 30-minute period.

2.8.3.5 A poststorage performance check was conducted to ensure proper operation of the IVAC® Model 580+EE.

2.8.4 Test findings

2.8.4.1 The pretest performance check met criterion 2.1.2.2.

2.8.4.2 No operational failures occurred during the low-temperature test. Criterion met.

2.8.4.3 The posttest performance check met criterion 2.1.2.2.

2.8.4.4 The IVAC® Model 580+EE functioned properly after the low-temperature storage test. Criterion met.

2.9 HUMIDITY TEST [IAW MIL-STD-810D, METHOD 507.2]

2.9.1 Objective

To determine the ability of the IVAC® Model 580+EE to operate satisfactorily for short periods of time during exposure to highly humid conditions.

2.9.2 Criterion

The IVAC® Model 580+EE will display consistent and accurate performance while exposed to a high humidity environment.

2.9.3 Test procedure

2.9.3.1 A pretest performance check was conducted to ensure the proper operation of the IVAC® Model 580+EE.

2.9.3.2 The humidity test was conducted in a Tenney Engineering model ZWUL-10107D walk-in controlled environment chamber*. This test is based on MIL-STD-810D, Method 507.2. For the humidity test, the IVAC® Model 580+EE was placed in operation on the floor of the environmental chamber. The chamber temperature was raised to a temperature of 30°C and a relative humidity of 95 percent within 25 minutes. Temperature and relative humidity were maintained for 4 hours. The environmental control system is capable of regulating temperature within $\pm 2^\circ\text{C}$ and humidity within ± 5 percent RH. At 45-minute intervals the performance of the BP monitor was checked. The chamber door was opened briefly to minimize the change in chamber conditions. The chamber and

the IVAC® Model 580+EE were returned to ambient conditions before the posttest performance validation check was conducted.

2.9.3.3 A posttest performance check was conducted to ensure the proper operation of the IVAC® Model 580+EE.

2.9.4 Test findings

2.9.4.1 The pretest performance check met criterion 2.1.2.2.

2.9.4.2 The IVAC® Model 580+EE detected an internal malfunction when operating in the ac power mode during the humidity test. No errors were detected when operated on battery power for this test. Criterion not met.

2.9.4.3 The posttest performance check met criterion 2.1.2.2.

2.10 ELECTROMAGNETIC CHARACTERISTICS TEST [IAW MIL-STD-461A, Notice 4, and MIL-STD-462, Notice 3]

2.10.1 Objectives

2.10.1.1 To assess the maximum levels of radiated electromagnetic emissions produced by the IVAC® Model 580+EE in the 14 kHz to 12.4 GHz frequency range.

2.10.1.2 To assess the tolerances of radiated electromagnetic susceptibility of the IVAC® Model 580+EE within the 10 kHz to 10 GHz electric field.

2.10.1.3 To assess the maximum levels of conducted electromagnetic emissions produced by the IVAC® Model 580+EE in the 10 kHz to 50 MHz frequency range.

2.10.1.4 To assess the tolerances of conducted electromagnetic susceptibility of the IVAC® Model 580+EE within the range of 50 kHz to 400 MHz and power spikes.

2.10.2 Criteria

2.10.2.1 The IVAC® Model 580+EE will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.

2.10.2.2 The IVAC® Model 580+EE will not malfunction when it is subjected to radiated emissions as specified in MIL-STD-461A, Notice 4, paragraph 6.20.

2.10.2.3 The IVAC® Model 580+EE shall not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.

2.10.2.4 The IVAC® Model 580+EE shall not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.

2.10.3 Test procedure

2.10.3.1 The radiated emissions test was performed according to MIL-STD-462, Notice 3, Method RE02. The IVAC® Model 580+EE was positioned on a wooden test stand inside the EMI chamber, 1 meter away from the receiving antennas. The antennas were mounted for both vertical and horizontal polarities and connected to EMI receivers. While the IVAC® Model 580+EE was operating, the frequency spectrum (14 kHz to 12.4 GHz) was scanned for emissions. The IVAC® Model 580+EE was operated with both ac and battery power.

2.10.3.2 The radiated susceptibility test was performed according to MIL-STD-462, Notice 3, Method RS03. The IVAC® Model 580+EE was positioned on a wooden test stand inside the EMI chamber 1 meter away from the transmitting antennas. The antennas were mounted for both vertical and horizontal polarities and connected to radio frequency (RF) transmitters. While the IVAC® Model 580+EE was operating, it was monitored for faulty operation during exposures to fields of 1 V/m from 10 kHz to 2 MHz, and 5 V/m from 2 to 30 MHz, 10 V/m from 30 MHz to 2 GHz, and 5V/m from 2 to 10 GHz. The IVAC® Model 580+EE was operated with ac and battery power.

2.10.3.3 The conducted emissions tests were performed according to MIL-STD-462, Notice 3, Methods CE02 and CE04. The IVAC® Model 580+EE was placed on a grounded, copper covered workbench. The top of the workbench was 1 meter from floor level, 1.37 meters long and 0.81 meters wide. Power was supplied via a pair of line impedance stabilization networks (LISN) and a test jig. The test jig is a wooden tray with two power receptacles and two slots to hold current probes in place around power supply conductors. While the IVAC® Model 580+EE was operating, the frequency range (10 kHz to 50 MHz) was scanned for emissions conducted in the power cable.

2.10.3.4 The conducted susceptibility spike test was performed according to MIL-STD-462, Notice 3, Method CS06, on a chemical resistant counter top. Power was supplied via a customized metal connection box. The connection box has two power receptacles and four banana jacks on its front panel. Connections to the individual power lines are made in series through the banana jacks. Transient spikes of 100 volts, 10 microseconds were generated with a Solar Electronics model 8282-1 transient pulse generator* and induced onto the power leads at the connection box banana jacks. The spikes were monitored with a Tektronix 2235 oscilloscope* connected to a power receptacle on the connection box.

The IVAC® Model 580+EE was plugged into the other receptacle on the connection box and placed in operation. It was observed for correct operation and visual displays while it was subjected to the power line spikes.

2.10.3.5 The conducted susceptibility test was performed according to MIL-STD-462, Notice 3, Method CS02. The IVAC® Model 580+EE was placed on a grounded, copper covered workbench. Radio frequency interference was induced on the power leads and measured at the power cable. The frequency of the interference was incremented over the 50 kHz to 400 MHz range while the IVAC® Model 580+EE was operated. It was observed for correct operation and visual displays while it was subjected to the radio interference on the power leads. Each frequency was held for 15 seconds.

2.10.4 Test findings

2.10.4.1 During the radiated emissions test, emissions which exceeded specification limits of MIL-STD-461A, Notice 4, were detected. These included:

<u>Power</u>	<u>Frequency range</u>	<u>Emission exceeding standard</u>
ac:	0.166 - 479.050 MHz	0.0 - 43.9 dB (NB)
	0.014 - 0.110 MHz	1.0 - 17.4 dB (BB)
	0.598 - 200 MHz	0.4 - 1.50 dB (BB)
dc:	0.923 - 489.837 MHz	0.5 - 40.4 dB (NB)

Criterion not met.

2.10.4.2 The IVAC® Model 580+EE was found to be susceptible to radio frequency interference in the testing range and magnitude.

<u>Frequency range</u>	<u>Maximum field strength without susceptibility</u>
16.4 - 24.0 MHz	0.95 - 4.72 V/m
30.0 - 200 MHz	0.24 - 9.23 V/m
228 - 388 MHz	2.69 - 9.44 V/m
460 - 904 MHz	4.22 - 9.89 V/m

Criterion partially met.

2.10.4.3 Narrowband emissions of 0.3 and 3.5 dB over specification were detected at 16.5683 and 44.091 MHz. A broadband emission of 1.3 dB over specification was detected at 1.659 MHz. Criterion not met.

2.10.4.4 The test signals were not detectable on the power lines due to conducted emissions from the IVAC® Model 580+EE. Criterion not met.

2.11 IN-FLIGHT HUMAN FACTORS EVALUATION

2.11.1 Objective

To assess the physical and/or functional compatibility of the IVAC® Model 580+EE while in use on board the aircraft.

2.11.2 Criterion

The flight surgeon will be able to operate the IVAC® Model 580+EE without physical or functional restrictions aboard the aircraft. Major areas of concern include: Proper operation, visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.

2.11.3 Test procedure

Not applicable since unit not available for in-flight testing.

2.11.4 Test findings

Not available since unit not available for in-flight testing. Criterion not evaluated.

Section 3. Supporting documentation

3.1 DETAILED TEST INFORMATION

3.1.1 General information

3.1.1.1 IVAC® Model 580+EE testing is not considered a major action significantly affecting the quality of the human environment and, therefore, qualifies for categorical exclusion A-28, appendix A, AR 200-1.

3.1.1.2 A safety pilot will be designated for each flight. Flight operations will be conducted IAW the aircraft operator's manual, appropriate aircrew training manuals, and test item technical data.

3.1.2 Material description

3.1.2.1 The IVAC® Model 580+EE Volumetric infusion pump is electrically driven and designed to regulate IV fluids on a semiautomatic basis. Membrane switches on the front of the infusion pump allow the user to set the primary and secondary rate and volume of fluid to be administered. The rate adjustment range is from 1 to 500 ml/hr. The primary volume to be infused may be adjusted from 1 to 9999 milliliters and the secondary volume may be adjusted from 1 to 999 milliliters. When the selected volume has been delivered, an audio alarm is activated and the IVAC® 580+EE reverts to a "keep vein open" delivery rate of 5 ml/hr. A locking clear blue plastic door protects the administration set and the control mechanism. The infusion pump is automatically shut off if the door is opened during the infusion. A pole clamp, ac power receptacle, flow sensor storage bracket, flow sensor receptacle and an ac line circuit breaker are located on the back panel. The only administration set that will function properly with the IVAC® 580+EE is the IVAC® "Type S" administration set.

3.1.2.2 Method of operation: The IVAC® Model 580+EE is an electrically driven volumetric infusion pump. The microprocessor-based infusion pump uses a linear peristaltic mechanism to regulate the volume of fluid being infused. The locking clear blue plastic door covers the pulsatile mechanism and the "Type S" administration set. The flow sensor unit is attached to the drip chamber of the IV administration set and is able to detect erratic drops, which activate an error message and an audio alarm. The infusion pump automatically shuts down in this event. The front panel contains all of the membrane switches and indicators used in setting or adjusting the delivery rate or volume to be infused. The errors displayed on the unit

are "Flo" or "Flo" followed by a number, "Err" followed by a number or letter, "door", "hold", and "batt."

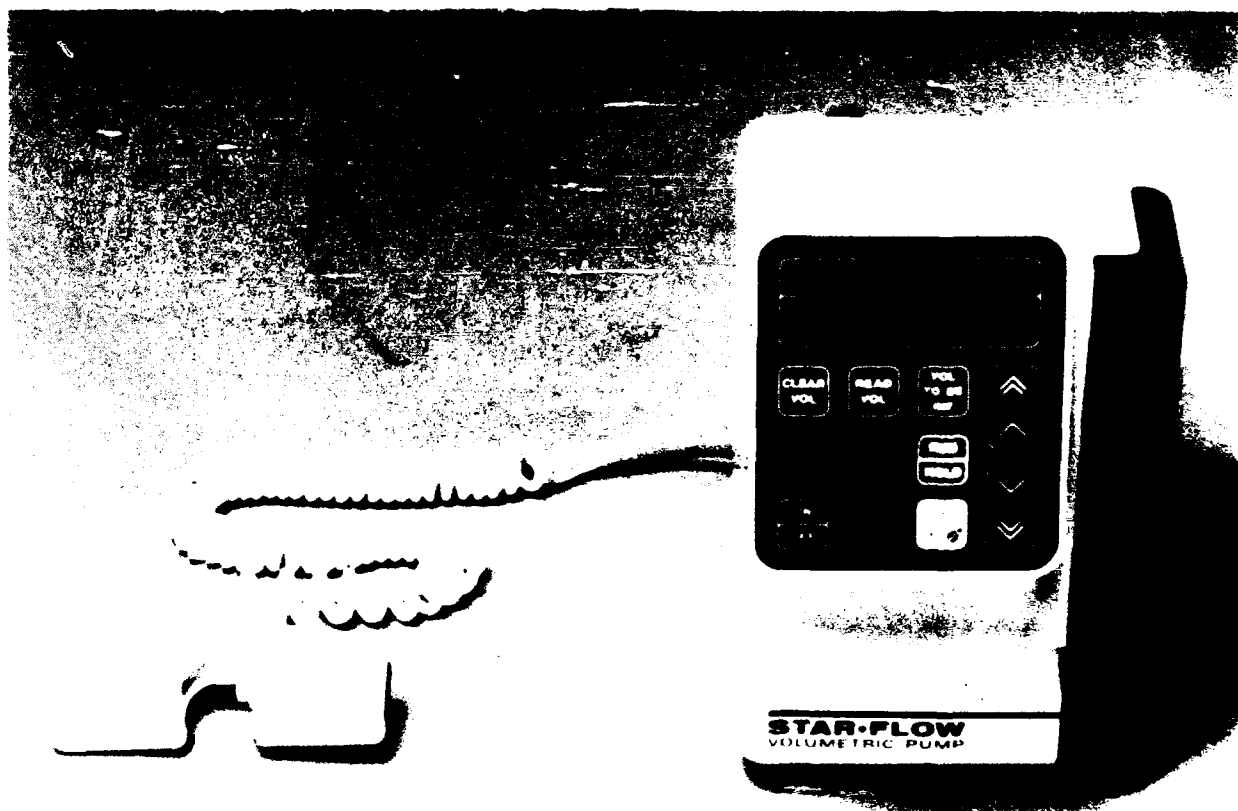
3.1.2.3 Dimensions: 5.1 x 7.2 x 7.6 in. (13 x 18.3 x 19.3 cm).

3.1.2.4 Weight: 6 lb (2.7 kg).

3.1.2.5 Power requirements: 90 to 126 Vac, 50 or 60 Hz, 0.15 amp, 3-wire grounded system. Internal rechargeable battery provides 6 hours of rated operation with the infusion pump set at a rate of 125 ml/hr. Charge time for a low battery to 70% of a full charge approximately 6 hours with the unit off. Power cord is 18-3, type SJT, PE CO, of approximately 119 inches in length.

3.2 TEST DATA

3.2.1 Photographic description



3.2.2 Aircraft equipment list

Item No.	Nomenclature
1	Receiver radio -- R-1496A/ARN-89 (automatic direction finder)
2	Displacement gyro -- CN-1314/A
3	Gyro directional -- CN-998/ASN-43
4	Signal data converter -- CV-3338/ASN-128
5	Receiver -- R-2139/ARN-123 (VOR/LOC/MB/GS)
6	Command instrument system processor -- 70600-01038-101
7	SAS amplifier -- 70901-02908-104 (flight control stability augmentation system)
8	Rate gyro -- TRU-2A/A
9	Amplifier, impedance -- AM-4859A/ARN-89
10	Cargo hook -- FE-7590-145
11	Receiver, radar -- RT-1193/ASN-128 (doppler navigation receiver)
12	Barometric altimeter -- AAU-31/A-1
13	Barometric altimeter -- AAU-32A
14	Receiver/transmitter -- RT-1300/ARC-186 (VHF-AM and/or FM radio)
15	UHF-AM radio set -- RT-1518/ARC-164
16	Interphone control -- C6533/ARC (aircraft intercom control)
17	Receiver/transmitter -- RT-1115D/APN-209 (radar altimeter)
18	Indicator altimeter -- ID-1917C/APN-209 (radar altimeter)
19	Control radio set -- C-7392A/ARN-89 (automatic direction finder)
20	Comparator signal data -- CM-482/ARC-186 (comparator for ARC-186)
21	Receiver/transmitter -- RT-1296A/APX-100 (transponder with IFF)
22	Computer display unit -- CP-1252/ASN-128 (doppler navigation system)
23	Compass set infusion pump -- C-8021E/ASN75
24	Magnetic compass - standby -- MS-17983-4

3.2.3 Battery life evaluation

Battery Life Evaluation Report Form

Nomenclature: Volumetric infusion pump

Manufacturer: IVAC® Inc.

Model number: IVAC® Model 580+EE

Serial number: 580+-8709

Military item number: None

Options installed: None

Manufacturer battery life specification: 6 hours

Specified battery recharge time: 6 hours (70% charge).

Specified mode of operation under battery power: 125 ml/hr
infusion rate.

Overall performance: Pass

Measurements: The unit averaged 7 hours and 8 minutes of
operation.

Comments: None

3.2.4 Electrical safety test

Electrical Safety Test Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 4 Apr 89

Measurements:

Grounding conductor resistance (milliohms): 70.5

Leakage current - Case to ground (microamperes):

unit off, grounded, normal polarity	0.2
unit off, ungrounded, normal polarity	0.3
unit off, ungrounded, reverse polarity	0.3
unit on, grounded, normal polarity	0.2
unit on, ungrounded, normal polarity	0.3
unit on, ungrounded, reverse polarity	0.3

MAXIMUM LIMITS:

ground resistance (milliohms):	150
current (grounded, type A unit):	10
current (ungrounded, type A unit):	100
current (grounded, type B unit):	50
current (ungrounded, type B unit):	500

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: None

3.2.5 Human factors evaluation

Human Factors Evaluation Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 6 Apr 89

Item configuration during test: Item prepared for operation,
sitting on a counter top.

Checklist for HFE

RESULTS

VISUAL DISPLAYS:

Unsatisfactory

- display type, format, content
- location of displays
- indicator lights
- scalar displays
- color coding
- legends and labels
- cathode ray tubes
- counters
- flags, go-no-go, center-null indicators

Comments: Scalar displays and cathode ray tubes (CRT) are not applicable. The LED's are red in color and have no brightness controls. Controls are not illuminated for low light conditions.

CONTROLS:

Satisfactory

- location
- characteristics of controls
- labeling
- control - display relationships

Comments: It may be necessary to brace the infusion pump when pressing the membrane switches.

TIME REQUIRED TO PREPARE FOR OPERATION (list in comment)

Comments: 2.5 to 3 minutes required to prepare for operation.

MAINTAINABILITY:

Satisfactory

- component location
- component characteristics
- rests and stands
- covers, cases, access doors
- handles
- lubrication
- component mounting
- cord storage provisions
- external accessibility
- internal accessibility
- list special tools required
- list realistic inspection requirements
- list realistic inspection intervals

Comments: There is an internal self-test with each power-up. A 6-month inspection list is found in the operator's manual. There is no lubrication or need for internal accessibility.

CONDUCTORS:

Satisfactory

- binding and securing
- length
- protection
- routing
- conductor coding
- fabrication
- connectors

Comments: None

FASTENERS:

Satisfactory

- access through inspection panel covers
- enclosure fasteners
- device mounting bolts and fasteners

Comments: An IV pole clamp is built in on the rear panel.

TEST POINTS:

Satisfactory

general
location and mounting
test point labeling and coding

Comments: None

TEST EQUIPMENT:

Satisfactory

general
equipment self-test
indicators (list in comments)
controls
positive indication of proper operation

Comments: An internal self-test outputs codes for
normal status and for failures.

FUSES AND CIRCUIT BREAKERS:

Satisfactory

external accessibility
easy replacement or reset by operator

Comments: None

LABELS and CODING:

Satisfactory

placed above controls and displays
near or on the items they identify
not obscured by other equipment components
describe the function of the items they identify
readable from normal operating distance
conspicuous placards adjacent to hazardous items

Comments: None

SAFETY:

Satisfactory

manual
materials
fire and explosive protection
operator protection from mechanical hazards
patient protection from mechanical hazards
electrical safety (operator and patient)

Comments: The unit is enclosed in a nonconducting
plastic case.

3.2.6 Altitude test

Altitude Test Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 11 Apr 89

Item configuration during test: Item operating at 70 ml/hr on battery power, sitting on chamber floor.

Performance test criteria: Consistent and accurate displays and measurements

Ambient conditions outside chamber:

Temperature	64°F
Humidity	55% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None (battery)
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	ac

IN-TEST DATA

Time of test start: 0810

POSTTEST DATA

Posttest performance check (complete check of item and accessories):

Time of test end: 0935

Item functional (based on performance test criteria): Yes

Deviation from pretest : None

Comments on item setup or checks: None

Comments on test run (including interruptions): Air in line noted due to change in pressure to reach 15,000 ft.

Comments on other data: Variations in pressure caused the drip chamber to become filled with bubbles. Bubbles did not form when the unit was held at a constant altitude. The drip chamber again filled with bubbles while returning to ambient conditions.

3.2.7 Vibration test

Vibration Test Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 10 Apr 89

Item configuration during test: Item strapped down on vibration table fixture; ac and dc operation.

Performance test criteria: Consistent and accurate measurements and displays.

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None

Ambient conditions

Temperature	68°F
Humidity	58% RH
Barometric pressure	1 atm

IN-TEST DATA

Data and performance checks during test:

Time at first check:

X: 1220 (4-10-89) Y: 1320 (4-10-89) Z: 1015 (4-11-89)

Item functional (based on performance test criteria): No

Deviation from pretest: Internal error alarms during vibration in Y and Z axis.

Time at second check:

X: 1310

Y: 1410

Z: 1110

Item functional (based on performance test criteria): No

Deviation from pretest: Internal error alarms during
vibration in Y and Z axes.

POSTTEST DATA

Time at test end:

X: 1320

Y: 1420

Z: 1115

Posttest performance check (complete check of item and accessories):

Item functional (based on performance test criteria): Yes

Item intact: Yes

Deviation from pretest: None

Comments on item setup or checks:

The unit showed "err.a" and "err.5" during the test runs
in the y and z axes. The unit was reset each time.

Comments on test run (including interruptions): None

Comments on other data: A Dynatech Nevada infusion pump
analyzer and volumetric chamber were used to measure the
infusion rate of the unit.

3.2.8 High temperature test

High Temperature Test (Equipment Operating) Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 10 May 89

Item configuration during test: Unit was sitting on chamber floor, operated on ac and battery power at a rate of 70 ml/hr.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	61% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check :

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

IN-TEST DATA

Time of test start: 0815

Performance checks during test:

First check:

Time: 0845
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
No, "Err.1" flashing
Deviation from pretest: None

Second check:

Time: 0915
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
No, "Err.1" flashing
Deviation from pretest: None

Third check:

Time: 0945
Temperature: 49°C
Humidity: 15% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria):
No, "Err.1" flashing
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:

(complete check of item and accessories)

Time of test end: 1040
Item functional (based on performance test criteria):
No, "Err.1" flashing
Deviation from pretest: None

Comments on item setup or checks: "Err.1" indicates an internal malfunction and the pump is automatically shut off.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.9 High temperature storage test

High Temperature Test (Equipment in Storage) Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 11 May 89

Item configuration during test: Sitting on chamber floor, in storage, not operating.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	50% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

Time of test start: 0745

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1445
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks:
The unit was allowed to cool overnight, before the posttest performance check was completed.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.10 Low temperature test

Low Temperature Test (Equipment Operating) Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 10 May 89

Item configuration during test: Sitting on test stand, operating on ac and battery power at 70 ml/hr.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	23°C
Humidity	not available
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Pass

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

Time of test start: 1100

Performance checks during test:

First check:

Time: 1130
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Second check:

Time: 1200
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Third check:

Time: 1230
Temperature: 0°C
Humidity: NA
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

POSTTEST DATA

Posttest performance check:
(complete check of item and accessories)

Time of test end: 1315
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Comments on item setup or checks:

While returning to ambient conditions, condensation formed on the drip chamber and caused the unit to alarm.

Comments on test run (including interruptions): None

Comments on other data: None

3.2.11 Low temperature storage test

Low Temperature Test (Equipment in Storage) Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 12 May 89

Item configuration during test: The unit is in storage,
not operating.

Performance test criteria: Consistent and accurate displays and
measurements

Ambient conditions outside chamber:

Temperature	23°C
Humidity	50% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	None
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	All
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

Time of test start:	0800
Midtest time:	1130
Midtest temperature:	-46°C

POSTTEST DATA

Posttest performance check:

(complete check of item and accessories)

Time of test end: 1500

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): None

Comments on other data: The unit was allowed to return to
ambient conditions overnight before final performance check.

3.2.12 Humidity test

Humidity Test Report Form

Nomenclature: Volumetric infusion pump
Manufacturer: IVAC® Inc.
Model number: IVAC® Model 580+EE
Serial number: 580+-8709
Military item number: None

Options installed: None

Date of test: 15 May 89

Item configuration during test: The unit was sitting on a test stand, operating at 70 ml/hr.

Performance test criteria: Consistent and accurate displays and measurements.

Ambient conditions outside chamber:

Temperature	24°C
Humidity	62% RH
Barometric pressure	1 atm

PRETEST DATA

Pretest performance check:

Item functional (based on performance test criteria): Yes

Installation of item in test facility:

list connections to power	120 Vac
list connections to simulators	None
list connections to dummy loads	None
list unconnected terminals	None
distance from north wall (meters)	0.6223
distance from south wall (meters)	0.5334
distance from east wall (meters)	1.4986
distance from west wall (meters)	1.2446
distance from ceiling (meters)	1.3208
distance from floor (meters)	0.4826

IN-TEST DATA

Time of test start: 0845

Performance checks during test:

First check:

Time: 0930
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Second check:

Time: 1015
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Third check:

Time: 1100
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Fourth check:

Time: 1145
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): Yes
Deviation from pretest: None

Fifth check:

Time: 1230
Temperature: 29.5°C
Humidity: 95% RH
Barometric pressure: 1 atm
Item functional (based on performance test criteria): No
Deviation from pretest: Internal error alarm during ac operation.

POSTTEST DATA

Posttest performance check:

(complete check of item and accessories)

Time of test end: 1400

Item functional (based on performance test criteria): Yes

Deviation from pretest: None

Comments on item setup or checks: None

Comments on test run (including interruptions): The unit operated properly on battery power, but "err.1" was detected on the fifth check during ac power operation.

Comments on other data: None

3.2.13 Electromagnetic characteristics test

Electromagnetic Characteristics Testing Evaluation of Performance

T & E Item Number: 14

Date: 12 Apr 89

Nomenclature: Volumetric infusion pump

Manufacturer: IVAC® Inc.

Model number: IVAC® Model 580+EE

Serial number: 580+-8709

Military item number: NA

Conducted Emissions Tests

CE01 Testing configuration(s): NA
 Performance (pass/fail): NA

Comments: NA

CE02 Testing configuration(s): Operating on copper work
 bench at 70 ml/hr.
 Performance (pass/fail): Pass

Comments: No signal failures.

CE04 Testing configuration(s): Operating on copper work
 bench.
 Performance (pass/fail): Fail

Comments: NB failure 0.8 to 3.5 dB over specifications at 16.568 to 44.091 MHz. Broadband emission of 1.3 dB over specification at 1.659 MHz.

Conducted Susceptibility Tests

CS02 Testing configuration(s): Operating on test bench,
 connected to test jig.
 Performance (pass/fail): NA

Comments: Unable to test because noise generated by the unit is greater than the test signal (unable to measure test signal).

CS06 Testing configuration(s): Operating on counter
 top.
 Performance (pass/fail): Pass

 Comments: Not susceptible to test spikes

Radiated Emissions Tests

RE02 Testing configuration(s): Operating on wooden test
 stand in the EMC chamber, ac and battery power.
 Performance (pass/fail): Fail

 Comments: ac operating failure data:
 NB failures 0.0 to 43.9 dB over specifications in
 range 0.166 to 479.050 MHz; BB failures of 1.0 to
 17.4 dB over specification in range 0.014 to .110
 MHz and 0.4 - 1.5 dB from 0.598 - 200 MHz.

 Battery operating failure data:
 NB failures 0.5 to 40.4 dB over specifications from
 0.923 - 489.837 MHz.

Radiated Susceptibility Tests

RS03 Testing configuration(s): Operating on the wooden
 test stand in the EMC chamber, ac power only.
 Performance (pass/fail): Fail

 Comments: Susceptibility data:
 0.95 - 5.42 V/m from 16.4 - 24 MHz
 0.24 - 9.23 V/m from 30 - 200 MHz
 2.69 - 9.44 V/m from 226 - 388 MHz
 4.22 - 9.89 V/m from 460 - 904 MHz

3.3 CRITERIA, SIGNIFICANT PROBLEMS, AND SUGGESTED IMPROVEMENTS

3.3.1 Criteria

Item		<u>Applicable</u>	
<u>No.</u>	<u>Criteria (source)</u>	<u>Remarks</u>	<u>subparagraph</u>
1	The physical inventory is conducted solely for investigation and documentation.	NA	2.1.2.1
2	The IVAC® Model 580+EE will display consistent and accurate measurements.	met	2.1.2.2
3	Verify manufacturer's specified full power internal battery life expectancy of 6 hours.	met	2.2.2
4	The IVAC® Model 580+EE will meet the limits established in TB 38-750-2 for electrical safety of medical equipment.	met	2.3.2
5	The IVAC® Model 580+EE will be rated satisfactory in all major categories of the evaluation. These include: Visual displays, controls, maintainability, conductors, fasteners, test points, test equipment, fuses and circuit breakers, labels and coding, and safety.	partially met	2.4.2
6	The IVAC® Model 580+EE will display consistent and accurate measurements while exposed to an altitude equivalency of 15,000 feet above sea level.	not met	2.5.2
7	The IVAC® Model 580+EE will remain operational and display consistent and accurate measurements while exposed to vibrational stresses.	not met	2.6.2

8	The IVAC® Model 580+EE will display consistent and accurate measurements during the high temperature operation check.	not met	2.7.2.1
9	The IVAC® Model 580+EE will display consistent and accurate measurements after the high temperature storage.	met	2.7.2.2
10	The IVAC® Model 580+EE will display consistent and accurate measurements during the low temperature operation check.	met	2.8.2.1
11	The IVAC® Model 580+EE will display consistent and accurate measurements after the low temperature storage.	met	2.8.2.2
12	The IVAC® Model 580+EE will display consistent and accurate measurements while exposed to a high humidity.	not met	2.9.2
13	The IVAC® Model 580+EE will not produce emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraph 6.13.	not met	2.10.2.1
14	The IVAC® Model 580+EE will not malfunction when it is subjected to radiated fields as specified in MIL-STD-461A, Notice 4, paragraph 6.20.	partially met	2.10.2.2
15	The IVAC® Model 580+EE will not conduct emissions in excess of the limits set forth in MIL-STD-461A, Notice 4, paragraphs 6.1 and 6.2.	not met	2.10.2.3
16	The IVAC® Model 580+EE will not malfunction when it is subjected to conducted emissions as specified in MIL-STD-461A, Notice 4, paragraphs 6.7 and 6.10.	not met	2.10.2.4

3.3.2 Significant problems which require corrective action

3.3.2.1 Problems associated with filling of the drip chamber during ascent to altitude and bubble formation in administration set should be corrected.

3.3.2.2 The unit should function properly in response to vibration in the Y and Z axes.

3.3.2.3 The unit should not suffer internal errors when operating in a high temperature environment.

3.3.2.4 The unit should not suffer internal errors when operating in a humid environment.

3.3.2.5 Additional shielding will be needed to reduce the electromagnetic emissions produced by the unit. This shielding may also reduce the susceptibility of the device to electromagnetic emissions.

3.4 REFERENCES

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3.4.4 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, DC. TB 38-750-2. April.

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3.4.6 Association for the Advancement of Medical Instruments. Human factors engineering guidelines and preferred practices for the design of medical devices. Arlington, Virginia. AAMI-HE-1988. February.

3.4.7 Department of the Army. 1987. Maintenance management procedures for medical equipment. Washington, DC. TB 38-750-2. April.

3.4.8 National Fire Protection Association. 1987. Standard for health care facilities. Quincy, Massachusetts. February. NAFF 99.

3.4.9 Mitchell, G. W., and Adams, J. E. 1988. Technical test and evaluation of aeromedical equipment. Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory. USAARL Letter Report LR-88-16-1-2.

3.5 ABBREVIATIONS

ac	alternating current
AEST	aeromedical equipment suitability test
AVSCOM	U.S. Army Aviation Systems Command
AWR	airworthiness release
BB	broadband
BP	blood pressure
BPM	beats per minute
CAAF	Cairns Army Airfield
CRT	cathode ray tube
dB	decibel
dc	direct current
ECG	electrocardiograph
EMC	electromagnetic compatibility
EMI	electromagnetic interference
fpm	feet per minute
GFE	government furnished equipment
Gpk	gravity, peak
G(rms)	gravity (root mean square)
Hz	hertz
IAW	in accordance with
ITOP	in-flight test operating procedure
IGE	in-ground effect
IVAC* 580+EE	IVAC* Inc. volumetric infusion pump
kg	kilogram
kHz	kilohertz
KIAS	knots indicated airspeed
lb	pound
LCD	liquid crystal display
LED	light emitting diode
LISN	line impedance stabilization network
MAP	mean arterial pressure
MEDEVAC	medical evacuation
MHz	megahertz
MIL-STD	military standard
mL	milliliter
mm	millimeter
mmHg	millimeters of mercury
MSL	mean sea level

NA	not applicable
NAFP	National Association of Fire Prevention
NB	narrowband
NBC	nuclear, biological, and chemical
NiCad	nickel cadmium
NOE	nap-of-the-earth
NVG	night vision goggle
RAM	random access memory
RF	radio frequency
RH	relative humidity
ROM	read only memory
TB	technical bulletin
TFT	technical feasibility testing
T & E	test and evaluation
UES	Universal Energy Systems, Inc.
USAARL	U.S. Army Aeromedical Research Laboratory
V/m	volts per meter

3.6 LIST OF MANUFACTURERS

- 3.6.1 IVAC® Corporation
10300 Campus Point Drive
San Diego, CA 92121-1579
- 3.6.2 Sikorsky Aircraft
6900 Main Street
Stratford, CT 06601
- 3.6.3 Neurodyne-Dempsey, Inc.
200 Arrowhead Drive
Carson City, NV 89701
- 3.6.4 Tenney Engineering, Inc.
1090 Springfield Road
P.O. Box 3142
Union, NJ 07083
- 3.6.5 Unholtz-Dickey Corporation
6 Brookside Drive
Wallingford, CT 06492
- 3.6.6 Solar Electronics Company
901 North Highland Avenue
Hollywood, CA 90038
- 3.6.7 Tektronix, Inc.
P.O. Box 500
Beaverton, OR 97077

3.7 DISTRIBUTION LIST

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APO New York 09180

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Research and Development Command
National Naval Medical Center
Bethesda, MD 20814-5044

Deputy Director, Defense Research
and Engineering
ATTN: Military Assistant
for Medical and Life Sciences
Washington, DC 20301-3080

Commander, U.S. Army Research
Institute of Environmental Medicine
Natick, MA 01760

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MD 21010-5425

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Fort Detrick, Frederick, MD 21702-5012

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Office of Naval Research
600 North Quincy Street
Arlington, VA 22217

Commander
U.S. Army Materiel Command
ATTN: AMCDE-XS
5001 Eisenhower Avenue
Alexandria, VA 22333

Commandant
U.S. Army Aviation
Logistics School ATTN: ATSQ-TDN
Fort Eustis, VA 23604

Headquarters (ATMD)
U.S. Army Training
and Doctrine Command
Fort Monroe, VA 23651

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Institute Library
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Wright-Patterson
Air Force Base, OH 45433

Henry L. Taylor
Director, Institute of Aviation
University of Illinois-Willard Airport
Savoy, IL 61874

COL Craig L. Urbauer, Chief
Office of Army Surgeon General
National Guard Bureau
Washington, DC 50310-2500

Commander
U.S. Army Aviation Systems Command
ATTN: SGRD-UAX-AL (MAJ Gillette)
4300 Goodfellow Blvd., Building 105
St. Louis, MO 63120

U.S. Army Aviation Systems Command
Library and Information Center Branch
ATTN: AMSAV-DIL
4300 Goodfellow Boulevard
St. Louis, MO 63120

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Library AAM-400A
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Oklahoma City, OK 73125

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U.S. Army Academy
of Health Sciences
ATTN: Library
Fort Sam Houston, TX 78234

Commander
U.S. Army Institute of Surgical Research
ATTN: SGRD-USM (Jan Duke)
Fort Sam Houston, TX 78234-6200

AAMRL/HEX
Wright-Patterson
Air Force Base, OH 45433

John A. Dellinger,
Southwest Research Institute
P. O. Box 28510
San Antonio, TX 78284

Product Manager
Aviation Life Support Equipment
ATTN: AMCPM-ALSE
4300 Goodfellow Boulevard
St. Louis, MO 63120-1798

Commander
U.S. Army Aviation
Systems Command
ATTN: AMSAV-ED
4300 Goodfellow Boulevard
St. Louis, MO 63120

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Naval Biodynamics Laboratory
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Presidio of San Francisco, CA 94129

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U.S. Army Aeromedical Center
Fort Rucker, AL 36362

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Dr. Diane Damos
Department of Human Factors
ISSM, USC
Los Angeles, CA 90089-0021

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Missile Range
ATTN: STEWS-IM-ST
White Sands Missile Range, NM 88002

U.S. Army Aviation Engineering
Flight Activity
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Ms. Sandra G. Hart
Ames Research Center
MS 262-3
Moffett Field, CA 94035

Commander, Letterman Army Institute
of Research
ATTN: Medical Research Library
Presidio of San Francisco, CA 94129

COL Eugene S. Channing, O.D.
Brooke Army Medical Center
ATTN: HSHE-EAH-O
Fort Sam Houston, TX 78234-6200

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U.S. Army Medical Materiel
Development Activity
Fort Detrick, Frederick, MD 21702-5009

Commander
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Directorate of Combat Developments
Building 507
Fort Rucker, AL 36362

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Aviation R&D Activity
ATTN: PERI-IR
Fort Rucker, AL 36362

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Test Activity
ATTN: STEBG-MP-P
Cairns Army Air Field
Fort Rucker, AL 36362

Commander U.S. Army Medical Research
and Development Command
ATTN: SGRD-PLC (COL Sedge)
Fort Detrick, Frederick, MD 21702

MAJ John Wilson
TRADOC Aviation LO
Embassy of the United States
APO New York 09777

Netherlands Army Liaison Office
Building 602
Fort Rucker, AL 36362

British Army Liaison Office
Building 602
Fort Rucker, AL 36362

Italian Army Liaison Office
Building 602
Fort Rucker, AL 36362

Directorate of Training Development
Building 502
Fort Rucker, AL 36362

Chief
USAHEL/USAAVNC Field Office
P. O. Box 716
Fort Rucker, AL 36362-5349

Commander U.S. Army Aviation Center
and Fort Rucker
ATTN: ATZQ-CG
Fort Rucker, AL 36362

Commander/President
TEXCOM Aviation Board
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MAJ Terry Newman
Canadian Army Liaison Office
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Fort Rucker, AL 36362

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Building 602
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LTC Patrice Cottebrune
French Army Liaison Office
USAAVNC (Building 602)
Fort Rucker, AL 36362-5021

Brazilian Army Liaison Office
Building 602
Fort Rucker, AL 36362

Australian Army Liaison Office
Building 602
Fort Rucker, AL 36362

Dr. Garrison Rapmund
6 Burning Tree Court
Bethesda, MD 20817

Commandant Royal Air Force
Institute of Aviation Medicine
Farnborough Hants UK GU14 6SZ
Dr. A. Kornfield, President
Biosearch Company
3016 Revere Road
Drexel Hill, PA 29026

Commander
U.S. Army Biomedical Research
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Dr. H. Dix Christensen
Bio-Medical Science Building, Room 753
Post Office Box 26901
Oklahoma City, OK 73190

Dr. Christine Schlichting
Behavioral Sciences Department
Box 900, NAVUBASE NLON
Groton, CT 06349-5900

Commandant
Academy of Health Sciences
ATTN: HSHA-COM (LTC Huether)
Fort Sam Houston, TX 78234

U.S. Air Force Armament
Development and Test Center
Eglin Air Force Base, FL 32542

COL Eugene S. Channing, O.D.
Brooke Army Medical Center
ATTN: HSHE-EAH-O
Fort Sam Houston, TX 78234-6200